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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/782,520	02/14/2001	Geraldine Lerebour	BJS-2365-28	7537
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NIXON & VANDERHYE, PC 901 NORTH GLEBE ROAD, 11TH FLOOR ARLINGTON, VA 22203			EXAMINER KIM, JENNIFER M	
			ART UNIT 1617	PAPER NUMBER
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 09/782,520	<b>Applicant(s)</b> LEREBOUR ET AL.	
	<b>Examiner</b> Jennifer Kim	<b>Art Unit</b> 1617	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 06 June 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 13-36 is/are pending in the application.
- 4a) Of the above claim(s) 16 and 28-36 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 13-15 and 17-27 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

The response filed June 6, 2007 have been received and entered into the application.

### **Action Summary**

The rejection of claims 13-15 and 17-24 under 35 U.S.C. 103(a) as being unpatentable over Carson et al. (U.S.Patent No. 5,416,075) in view of Garofano (U.S.Patent No. 6,495,153 B2) is hereby expressly withdrawn in favor of modified rejection presented in this Office Action. The reference Garofano has been replace with Arai et al. (1996) because after the further consideration of the rejection, Arai et al. reference is deemed a stronger reference.

The rejection of claim 25 under 35 U.S.C. 103(a) as being unpatentable over Carson et al. (U.S.Patent No. 5,416,075) in view of Garofano (U.S.Patent No. 6,495,153 B2) as applied to claims 13-15 and 17-24 above and further in view of Cullinan (U.S.Patent No. 5,439,923) is hereby expressly withdrawn in favor of modified rejection presented in this Office Action. The reference Garofano has been replace with Arai et al. (1996) because after the further consideration of the rejection, Arai et al. reference is deemed a stronger reference.

Upon further consideration, additional rejection has been also made in this Office Action as follows:

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 13-15 and 17-27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The phrase "devoid of antibiotic, bacterial or fungicidal agents" in claim 13 renders the claim vague, indefinite and contradicting to the instantly claimed invention because the phrase excludes olive oil as an elected species of an active agent having an anti bacterial effect. One of ordinary skill in the art would recognize that olive oil as an antibiotic, bactericidal or fungicidal compounds because it is well known by Arai et al. (enclosed herein) that the claimed olive oil has inhibitory effects on the growth of bacteria such as *Staphylococcus aureus*.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 13-15 and 17-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Carson et al. (U.S. Patent No. 5,416,075) of record in view of Arai et al. (1996).

Carson et al. teach Oil-in-water emulsions comprising surfactants with biospecific headgroups. Carson et al. teach that the emulsion droplets **adhere** to surfaces of microorganisms or to various biological surface bearing appropriate adhesions, thus delivering surfactants materials directly to various surfaces. Carson et al. teach that emulsion contain oil droplets which serve as a substrate for an amphipatic compound

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including **olive oil**. (abstract, column 7, line 50 - column 8, line 1). Carson et al. teach that when the desired target surface is mammalian skin hair, or nails, suitable lipophilic materials include skin anti-ageing compound, skin conditioning compound, vitamins, perfumes, UV-absorbing materials, anti-acne agents, anticellulite compounds and mixtures thereof. Carson et al. teach the oil phase constitutes from 1% to 70%, preferably from 5% to 50%, most preferably from 10% to 30% by weight of the emulsion. (column 9, lines 59-62). These amounts are within Applicants' amount set forth in claim 18 and encompass the amount set forth in claim 19. Carson et al. teach that the composition can be formulated in the form of toothpaste, cream, or gels or mouthwashes. Column 10, lines 2-5). Carson et al. teach that the oil droplet in the emulsion provides polyvalent binding site for a microorganism or another cell on a biological surface, since numerous adhesin/receptor pairs are available to achieve adherence between a microorganisms or a biological surface and a biospecific amphipatic compound. (column 3, lines 55-61). Carson et al. teach that the emulsions may be incorporated into oral hygiene non-food compositions for compositions for topical application to skin, hair or nails. Carson et al. teaches that indigenous bacteria and other microorganisms (e.g. yeasts) present in an oral cavity or on other biological surfaces adhere to various substrates (e.g. microorganisms of the same or different genus, teeth surface, epithelial surface) via receptor-modulated recognition mechanisms and that microorganism in general express structure, generally termed "adhesions" which recognize and bind selectively to specific moieties called "receptors" found on microorganisms' surface or biological surfaces (e.g., teeth, oral cavity, skin,

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hair, or nails). Carson et al. teach that the adhesin/receptor modulated recognition mechanisms allow microorganisms to adhere with a high degree of selectivity and specificity to other microorganism (of same or different genus and/or species) and/or to a biological surface. Carson et al. teach that numerous skin microorganisms interact with epithelial substrates through receptor-modulated recognition between cells' surfaces and that various skin microorganisms adhere preferentially to specific sites on various body surfaces. (abstract, column 15-40, lines 50-55). Carson et al. teach that coaggregation reactions between complementary pairs of microorganisms or between microorganisms and biological surfaces can be inhibited by the presence in solution of the various moieties which are recognized by lectins and that competition for binding sites prevents or minimizes coaggregation to adherence. (column 2, lines 40-50).

Carson et al. do not expressly illustrate an example of the oil droplet emulsion employing olive oil and the mechanism of disrupting the ecological balance and the chemical characteristic of olive oil having a melting point of less than 35C and having an interfacial tension of between 6 and 27 mN/m.

Arai et al. teach that olive oil has inhibitory effects of staphylococcus aureus. Arai et al. teach that the olive oil has a potential use in skin care products for skin affected by atopic dermatitis. (abstract).

It would have been obvious to one of ordinary skill in the art to modify the teaching of Carson et al. by employing olive oil as a oil droplet component in the Carlson et al's emulsion because Carson et al. teach that olive oil can be employed in the emulsion to achieve adherence between a microorganism or a biological surface

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and because Arai et al. teach olive oil has a potential used in skin care product because of its inhibitory effect of bacteria. One would have been motivated to make such modification in order to achieve an expected benefit of olive oil conveniently having antibacterial activity as well as preventing the bacterial from adhering to skin by oily coating the surface of bacteria. There is an expectation of successfully reducing adherence of microorganism and disruption of ecological balance of the resident flora because olive oil is well known to have antibacterial activity and that olive oil composition reduces the adhesion of microorganisms to the surface of the skin by adhering to the microorganisms taught by Carson et al. Further, the chemical/physical characteristics of olive oil having a melting point of less than 35 degree C. and having the specified interfacial tension can be found with the same olive oil compound and within the same amounts taught by the cited references because the physical/chemical characteristic of a compound is inseparable. Moreover, the intentions such as to reduce body odors, to use for body hygiene health care or combat comedones and/or dandruff are all obvious because that indigenous bacteria and other microorganisms (e.g. yeasts (fungus)) that causes body odors, dandruff and mycosis would obviously be removed by Carson et al. as modified by Arai et al.

Claim 25 is rejected under 35 U.S.C. 103(a) as being unpatentable over Carson et al. (U.S. Patent No. 5,416,075) in view of Arai et al. (1996) as applied to claims 13-15 and 17-24 above and further in view of Cullinan (U.S. Patent No. 5,439,923).

Teachings of Carson et al. and Arai et al. as applied as before.



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Carson et al. and Arai et al. do not teach the resident flora of *Propionibacterium acnes* set forth in claim 25.

Cullinan teaches that common, indigenous skin principal bacteria is *propionibacterium Acnes*. (column 1, lines 35-37).

It would have been obvious to one of ordinary skill in the art at the time the invention was made that oil droplet emulsion taught by Carson et al. as modified by Arai et al. would disrupt the ecological balance of any indigenous skin bacteria particularly *Propionibacterium acnes* because Carson et al. teaches that the emulsion adheres to indigenous bacteria and other microorganism of the skin and because Cullinan teaches that common indigenous bacteria of skin is *propionibacterium Acnes*.

One would have been motivated to employ the emulsion composition taught by Carson et al. as modified by Arai et al. in order to disrupt and reduce adherence of most common skin indigenous bacteria of skin, *propionibacterium acnes*, in order to successfully achieve clean bacteria free skin in order to prevent the infection.

For these reasons the claimed subject matter is deemed to fail to patentably distinguish over the state of the art as represented by the cited references. The claims are therefore properly rejected under 35 U.S.C. 103.

None of the claims are allowed.

### **Response to Arguments**

Applicants' arguments filed June 6, 2007 have been fully considered but they are not persuasive. Applicants argue that Carson is understood to optionally include antimicrobial compound and that it would have been contrary to the preference of Carson for inclusion of antimicrobial compounds to provide a method, as claimed, which specifically excludes use of a composition containing antibiotic, bacterial or fungicidal agents. This is not found persuasive because as Applicants has correctly pointed out that the employment of antimicrobial compound in Carson's formulation is **optional** and that olive oil itself has an antimicrobial activity as taught by Arai et al. Therefore, one of ordinary skill in the art would not optionally would not employ additional antimicrobial agents since olive oil conveniently possesses antimicrobial activity. Applicants argue that the olive oil employed by Carson is not used as an active compound but rather as a vehicle to form oil droplets which serve as a substrate for the amphipathic compound and that Carson includes an amphipathic compound ingredient to present specific head groups which can be recognized by microorganisms. This is not found persuasive because Carson teaches that those droplets comprising olive oil that adhere to surfaces of microorganism and that a mechanism by which the active ingredient gives the same pharmacological effect does not alter the fact that the compound has been previously used to obtain the same pharmacological effects which would result from the claimed method. The patient, condition to be treated and the effect are the same. An explanation of why that effect occurs does not make novel or even unobvious the treatment of the conditions encompassed by the claims. Applicant argues that one of ordinary skill in the art would not have been motivated by Cullinan alone or in

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combination with Carson to have made the instantly claimed invention with a reasonable expectation of success because Cullinan teach that acne or seborrhea can be treated with administration of compound which not only bind to estrogen receptors but also contain estrogen agonist properties and display similar properties as estrogen, such a osteoporosis and hyperlipidemia. This is not found persuasive because Cullinan teaches that common principal indigenous skin bacterial is *propionibacterium Acnes* and that Carson teaches that their oil droplets adhere to this indigenous bacterial an and prevents from adhesion to the surface of the skin. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made that oil droplet emulsion taught by Carson et al. as modified by Arai et al. would disrupt the ecological balance of any indigenous skin bacterial particularly *Propionibacterium acnes* because they are common, principal indigenous bacterial found in skin as taught by Cullinan. There is a reasonable expectation of success because Carson et al. teaches that the oil droplets adhere to microorganisms and because Cullinan teaches that *Propionibacterium acnes* are principle indigenous bacteria commonly found skin. Thus, the claims fail to patentably distinguish over the state of the art as represented by the cited references.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Kim whose telephone number is 571-272-0628. The examiner can normally be reached on Monday through Friday 6:30 am to 3 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Jennifer Kim  
Patent Examiner  
Art Unit 1617

Jmk  
August 8, 2007